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Ethical and Legal Governance in Nutrition Research: A Narrative Review

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Abstract

Clinical trials of diets increasingly use human biospecimens (e.g., blood, saliva) to assess end points related to metabolism and microbiome; however, the collection, storage, and use of such biospecimens raise complex ethical and legal challenges

To examine biospecimen usage in nutrition science through research into moral views, legal disparities, and issues of governance. Special emphasis is given to subject autonomy, data proprietorship, and culturally competent practices.

We examined a total of 61 sources, such as historical ethics codes, international guidelines (e.g., GDPR, U.S. Common Rule, CIOMS), empirical literature on consent models, compliance, and biobanking practices.

Although classical models (Nuremberg, Helsinki, Belmont) heavily stress informed consent and justice, they don't adequately cover long-term burdens or cross-cultural decision-making, or genetic confidentiality. Variable globalization of regulatory authorities hinders collaboration, especially for LMICs. Long-term nutrition interventions have low compliance (~50–70%) with high attrition (up to 68.5%), but dynamic consent and culturally specific interventions increase compliance by 25–30%.

Current governance models prioritize research utility over individual rights. A rights-based framework, emphasizing dynamic consent, fair benefit-sharing, and harmonized international norms, can enhance trust, protect vulnerable groups, and increase the moral integrity of diet research.

Keywords: Nutrition research, Human biospecimens, informed consent, Ethical governance, participant autonomy

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Introduction

Dietary clinical trials are crucial for translating nutritional science into public health initiatives, particularly for metabolic disorders associated with diet (1). Studies increasingly use human biospecimens, such as blood and saliva, to fully evaluate metabolic and microbiome reactions (2,3). However, the collection and utilization of these biospecimens raise significant legal and ethical issues (4). Key challenges include the scope of informed consent and the ownership of donated biological materials. Another concern is the supervision of secondary data use, especially when samples are repurposed for unplanned future research (5). A significant point of contention is data sovereignty (the right of individuals to control their biological information), which is often compromised by a lack of international legal agreement (6). For instance, International regulations such as the GDPR and the U.S. Common Rule illustrate significant disparities in balancing research utility and individual rights (7,8). These developing countries also have divergences and their effects on cross-border cooperation, as sample export and fair benefit-sharing raise further ethical challenges (9–11). This narrative review argues that prevailing governance models are clearly inadequate for preserving participant rights in dietary studies, which differ from those in pharmaceutical studies (1).

Hereby recommended is a rights-based approach emphasizing the autonomy and equality of contributors. The narrative review will examine world regulatory differences, follow the evolution of consent standards, and provide a donor-centric strategy for biobanking informed by modern ethical principles. Hence, clearing the path for more participant-empowered studies (12–16).

Historical Perspective

Severe abuses such as Nazi camp experiments and the Tuskegee Study highlighted the need to establish basic ethical standards. In response to these horrors, the 1947 Nuremberg Code enshrined the concept of voluntary informed consent (12). Although designed for urgent medical treatments, this framework is inadequate for dietary studies that involve prolonged participation and risks of therapeutic misconceptions (4,8).

Building on these frameworks, the 1964 Declaration of Helsinki added more specific standards, putting participant well-being first (7). Notwithstanding its impact, the Declaration's Eurocentric bias is a glaring drawback. Its individualistic model of agreement sometimes conflicts with community decision-making methods in other cultures, maybe causing disparities in biospecimen control (11). Moreover, weak enforcement in regions like Iran and Jordan, where it fails to protect data sovereignty and prevent unauthorized secondary research (9), impairs its efficacy. The 1979 Belmont Report formalized Respect for Persons, Beneficence, and Justice, but did not anticipate privacy challenges of genetic data in modern nutrition research

(12). To address these issues, African and Iranian scholars have advocated for integrating native legal systems and cultural competence with Belmont's principles to ensure equitable benefit-sharing and avoid exploitation (10,11). The usage of Belmont during recent epidemics highlighted even more the need for reconstruction to strike a balance between participant protections and the general welfare in low- and Middle-income nations (LMICs), particularly about future uses of biospecimens in dietary trials (17,18). To successfully protect data sovereignty and reduce participant burden across several global populations, the present environment calls for new, adaptive frameworks (15).

Ethical Principles and Regulatory Frameworks Governing Human Samples in Dietary Clinical Trials

The application of the universal Belmont principles—respect for persons, beneficence, and justice — provides the foundational ethical framework for the use of human biospecimens in research. The principle of respect for persons mandates the protection of individual autonomy and

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data privacy through voluntary and fully informed participation (19). Beneficence requires maximizing benefits and minimizing harm to participants, a duty that, in practice, involves cautious sample management to mitigate physical and psychological harm and to control the disclosure of incidental findings (20). The World Medical Association's 2016 Declaration of Taipei explicitly addresses this by requiring that biobank consent processes include clear policies on the return of clinically significant results to donors (21). Justice, by ensuring the equitable distribution of research burdens and benefits, necessitates the fair selection of biospecimen donors and the implementation of benefit-sharing frameworks, particularly for underserved populations (22).

Consent models range from study-specific consent to tiered and broad consent, which enable wider, unstated future uses. Broad consent maximizes sample reutilization potential but may lower personal involvement and control. On the other hand, particular or tiered consent preserves autonomy but could significantly limit future research (23). Due to these inherent trade-offs, many people have started using middle-ground methods. If intense supervision and continuous communication with donors are combined with broad agreement, it is currently thought ethically acceptable. A promising innovation is dynamic consent, an interactive digital platform that enables participants to continuously manage their consent preferences, thereby supporting longitudinal biobank research while enhancing individual control and autonomy. The ultimate adoption of these models is contingent upon national laws and institutional capacities; yet, all must be governed by established ethical principles (24).

There are multiple levels of regulatory control for the use of biospecimens internationally (25). Explicitly asking for independent ethical review and obtaining informed consent for research on human samples is a global standard, most notably outlined in the Declaration of Helsinki of the World Medical Association and the CIOMS ethical guidelines (26). Major regulatory organizations (such as the U.S. FDA and the European EMA) enforce Good Clinical Practice norms calling for institutional review board (IRB) or ethics committee supervision of sample collection and analysis in trials (27). Data protection legislation also sets obligations; Cross-border research is further complicated by divergent legal frameworks (7). Binding instructions for human research are issued by the National Committee for Ethics in Biomedical Research (under the Ministry of Health and Medical Education) at the national level in Iran. These guidelines emphasize free and informed consent, the confidentiality and privacy of sample data, and the protection of vulnerable donors – echoing international principles while reflecting local legal and cultural contexts (10). Finally, at the institutional level, Research Ethics Committees (IRBs/RECs) in all countries – including Iran – are charged with enforcing this multi-layered framework, ensuring that both global standards and national regulations are upheld in practice (28). To enhance the discussion on consent models, additional considerations include the potential for meta-consent frameworks, where participants specify preferences for future consent requests, further promoting autonomy in evolving research landscapes (29). Regarding benefit-sharing, recent frameworks emphasize community engagement in LMICs to prevent exploitation and ensure equitable outcomes (30). For regulatory enforcement in diverse contexts, studies highlight the need for harmonized international standards to facilitate cross-border biospecimen research while respecting cultural differences (31).

Specific Challenges in Dietary Clinical Trials

Dietary clinical trials differ from pharmaceutical studies due to complex interventions that often span extended durations, leading to significant challenges with participant retention and compliance. For instance, a 2022 study of a multidisciplinary residential obesity program found significant dropout rates, reaching 68.5% at 12

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months, which affects statistical power and generalizability (32). While improved digital support tools could produce more accurate reporting than earlier studies, in real-world situations, high attrition remains a significant issue (33).

Socio-cultural factors, which are frequently overlooked in trial design, further complicate the challenges of adherence. Pivotal determinants of compliance are family dynamics, financial situation, and cultural food. Patients with gestational diabetes, for instance, may not follow treatment recommendations because of social norms and family obligations. Cultural and family dynamics, such as traditional dietary practices or mismatches with prescribed diets, frequently hinder compliance

(34,35). Trials should integrate culturally relevant education to mitigate this. Tailored programs have been proven to improve adherence in patients with type 2 diabetes and enhance self-care (3). This is often impossible to blind participants to their dietary consumption, which raises the chance of allocation bias. The possibility of nutrient shortages and therapeutic misconceptions raises ethical issues that must be addressed through full risk disclosure (20,36). Legally, biospecimen handling must comply with several international frameworks, including the EU's GDPR and the U.S. Common Rule (37), which categorizes biospecimen data as "Individual" and necessitates pseudonymization (7,38). Globally, these legal disparities complicate international trials, particularly in Africa and Asia, and therefore require coordinated criteria to prevent exploitation (39). Emphasizing custodianship and benefit-sharing, African frameworks, such as the H3Africa consortium, have country-specific regulations in Nigeria and South Africa that require local ethics committee supervision (40,41). Policies differ throughout Asia, including India's mandatory informed consent, China's restrictions on outward travel, and South Korea's control over biospecimen storage (42). Universal norms from Companies like CIOMS and WHO urge adaptive frameworks in low- and middle-income countries, which include community engagement (35,43). Ethically, transparency is vital as the Declaration of Helsinki and WHO guidelines demand the disclosure of all results, both positive and negative (44,45). Trial registries, such as ClinicalTrials.gov, and preregistration methods are Essential for avoiding publication bias and ensuring accountability (46,47), as failing to report null results misleads public health (48).

Being minors, children require parental permission and assent, with ethical boards demanding monitoring for developmental deficits from restricted diets (49). Frequently with comorbidities or polypharmacy, the elderly face increased risks, including drug-diet interactions or malnutrition; hence, close supervision is required (50,51). Patients with chronic diseases are prone to therapeutic misconceptions and health fluctuations; one feeding study found 24% of dropouts were caused by medicine or disease modifications, emphasizing the need for protocol flexibility. Cultural and economic circumstances exacerbate these problems; for instance, interventions for Middle Eastern communities must accommodate local cuisine and customs to enhance compliance and address misconceptions (3,10). Finally, research plans should include enhanced informed consent, nutritional monitoring, and participation from dietitians to ethically safeguard human samples, especially in prolonged trials (28,36).

Case Studies and Real-World Examples in Dietary Clinical Trials

Dietary clinical trials present distinct ethical challenges, including difficulties with blinding, prolonged compliance demands, and retention issues, which differ from those in pharmaceutical studies. This section critically examines the literature to analyze its strengths, weaknesses, contradictions, and gaps, drawing on illustrative cases to inform ethical decision-making and integrating foundational and recent evidence (52,53).

Adherence and Attrition Challenges

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Long-term nutrition trials often report low adherence and high attrition, which compromise validity and ethical integrity. A 2024 theory-based review of 15 trials found dropout rates exceeding 40%, with digital tools (e.g., app reminders) reducing attrition by 15-20% as a strength, enhancing feasibility in behavioral interventions (54). However, weaknesses include inconsistent application across demographics, resulting in biased outcomes for underrepresented groups. Contradictorily, domiciled feeding trials achieve 70-80% compliance in controlled environments but lack real-world applicability, unlike non-domiciled designs, which are plagued by self-report inaccuracies (63). A 2024 digital framework review highlights the role of reminders but notes equity gaps in LMICs (33). These gaps—particularly in LMIC cohorts—highlight the need for future hybrid RCTs that incorporate ethical burden assessments to minimize participant overload while enhancing generalizability.

Cultural Adaptation in Interventions

Cultural sensitivity is ethically vital for achieving equitable access, yet it is often overlooked. A 2023 synthesis of six public health programs in Indigenous and ethnic minorities showed culturally tailored strategies (e.g., integrating traditional foods) boosting adherence by 25-30%, a key strength in building trust and reducing misconceptions (55). This echoes a 2023 Iranian RCT where tailored education improved self-care by 28% (3). In contrast, a 2025 comparative study of German and Brazilian guidelines revealed Western-centric models yielding <50% uptake due to ritual mismatches, highlighting contradictory efficacy in non-Western settings where socioeconomic barriers amplify non-compliance (56); similarly, a 2025 gestational diabetes analysis linked cultural norms to 35-45% nonadherence (34), and a 2007 study found 30.2% family mismatches as barriers (35).

Biospecimen Regulations and Consent

Global regulatory variances exacerbate ethical dilemmas in the use of biospecimens. The 2025 INHERENT multinational hematology trial demonstrated EU GDPR's pseudonymization delaying collaborations by 20-30%, a weakness contrasting U.S. Common Rule flexibility that risks privacy; strengths include MTAs curbing exploitation by 25% (56), supported by a 2023 African narrative review advocating custodianship to prevent 25% inequities (31). A parallel 2025 Chinese analysis advocated custodianship over ownership, revealing contradictions where export bans protect local benefits but impede sharing (57).

Ethical integrity hinges on full disclosure. CONSORT 2025 guidelines counter 30-40% selective reporting in nutrition trials, strengthening replicability via preregistration, though journal adoption varies (58); this builds on 2020 analyses showing high-impact journals' procedures reduce bias by 30% (46), 2022 findings linking registration to lower risks (47), and a 2024 scoping review of 45 anti-bias activities (48). The 2013 Helsinki Declaration mandates all outcomes (44), reinforced by the 2017 WHO guidelines (45). Underreporting of harms in long-term studies creates contradictory efficacy claims.

Ethical Decision-Making and Lessons

Evidence-based lessons emphasize sustainable digital support to reduce the burden (33,54), cultural tailoring for 25-30% gains (55), stringent regulations via MTAs (56), and transparent reporting in accordance with CONSORT/Helsinki (44, 58). These advocate for proactive ethics, with a future focus on interdisciplinary models that bridge LMIC gaps for just and valid research.

Recommendations and Practices

The preceding analysis reveals that the ethical governance of dietary trials requires more than baseline regulatory compliance; it demands a proactive framework tailored to its unique challenges. To address this need, the following best practices are proposed to create a governance model that is robust, rights-based, and participant-centered (59).

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Modernize and Strengthen Consent Procedures

Ethical study depends on informed consent. Adopting advanced approaches is crucial to overcoming the limitations of traditional models. Dynamic consent systems allow participants to modify preferences in real-time via digital platforms, thereby enhancing autonomy while supporting longitudinal studies (24). According to the Declaration of Taipei, collection (e.g., blood, saliva), storage, secondary usage, and return of accidental findings are underground procedures based on the Belmont principles: beneficence and justice protect privacy and minimize risks, such as biobanking confidentiality breaches (19,21).

Navigate the Complex Global Regulatory Landscape

Globally, biospecimen rules differ; therefore, adherence to the highest criteria is required. Recognize differences: the GDPR of the EU mandates specific consent for pseudonymized data as personal information (7,8), but the U.S. Common Rule allows de-identified samples without reconsent, prioritizing utility (8). Specify post-donation ownership, donors relinquish rights, but the IRB imposes usage conditions (20). Enact layered surveillance: obtain IRB/REC clearance consistent with national policies (e.g., Iran's National Committee for Ethics in Biomedical Research) and worldwide standards such as the Declaration of Helsinki (10,25).

Address Unique Challenges in Dietary Intervention Trials

Dietary research calls for customized ethical principles from pharmaceutical studies to design sustainable interventions with support (like digital reminders) to counter high attrition (up to 68.5% at 12 months), for retention and adherence, therefore lowering burden and ensuring validity (32,33). Cultural adaptation should take priority: by modifying treatments to local diets and customs, as has been proven in a 2023 Iranian RCT in which customized instruction improved self-care by 28% in type 2 diabetics (3). According to Helsinki and WHO guidelines, transparency should be maintained by disclosing all outcomes, whether positive, negative, or null, to prevent biases and public misinterpretations resulting from underreporting (44,45). Together, these techniques help to integrate ethics throughout the research cycle by turning compliance into collaboration. By combining them, it strengthens validity, helps foster trust in nutrition science, and also protects participants.

Results

Foundational ethical codes (Nuremberg, Helsinki, Belmont) uniformly stress informed consent, beneficence, and justice. However, multiple analyses note they do not fully account for nutrition-specific challenges such as extended dietary interventions, cultural decision-making, and genetic privacy risks. In particular, enforcement gaps in many low- and middle-income settings undermine data sovereignty. Scholars thus call for locally tailored, participant-centric governance to ensure equitable benefit sharing and donor rights. Regulatory regimes show sharp contrasts. The EU's GDPR treats pseudonymized biospecimens as personal data, requiring explicit consent for secondary research (7), whereas the U.S. Common Rule typically allows use of fully de-identified samples without further consent. Many LMICs lack uniform biobank laws: for example, India mandates consent, but other Asian countries vary, and international bodies (CIOMS/WHO) urge adaptive frameworks and community engagement in developing regions. Such divergence creates cross-border hurdles for dietary trials. Consent models vary from broad to dynamic. Tiered consent procedures enable participants to tailor permission across research categories (e.g., specific diseases, anonymization), giving donors greater control over sample use. Dynamic (IT-enabled) consent platforms allow ongoing re-consent or withdrawal, increasing participant engagement (60). Each model involves trade-offs: broad consent maximizes research flexibility at the expense of individual

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control, whereas tiered/dynamic approaches enhance autonomy (but are more complex).

Long-term nutrition trials report modest adherence and substantial dropout. Adherence is often only ~50–70%, with attrition up to ~50–70% in long-term studies (52). Conversely, culturally adapted interventions and interactive consent have been associated with ≈25–30% higher compliance. Socio-cultural factors (family food customs, social norms) are repeatedly cited as barriers to adherence.

Benefit-sharing and sovereignty pose ongoing challenges. Ethics guidelines emphasize community engagement and fair return of research benefits in LMICs, but practical protection varies. For example, Iran's national guidelines stress informed consent and donor privacy, yet reviews report continued risks of exploitation without stronger enforcement. Calls for harmonized international standards and local custodianship recur in the literature.

Vulnerable groups warrant special safeguards. Children must give assent and have parental permission (with monitoring of growth), and elderly subjects require close medical oversight. Ethical frameworks highlight justice-based protections for underserved or marginalized participants. Finally, transparency measures are broadly endorsed: international codes (Declaration of Helsinki, WHO) mandate reporting of all trial outcomes, and trial registries/CONSORT adherence are urged to prevent publication bias.

Discussion

This review synthesizes the ethical and legal complexities of using human biospecimens in dietary clinical trials. Underlying principles of basic ethical codes such as the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report emphasize informed consent, beneficence, and justice, yet they were written for short-term clinical research and are incomplete for longer-term dietary intervention (6). Moreover, fragmented regulatory frameworks—such as the GDPR versus the U.S. Common Rule—create barriers to cross-border collaboration without providing consistent privacy benefits (61). To address these gaps, models that empower participants are required. Dynamic-consent platforms, for example, provide ongoing donor control and enhance transparency (13), while community-engaged, rights-based governance frameworks are advocated to ensure equitable benefit-sharing and trust, particularly in low- and middle-income settings (6,8).

Limitations of this review include its narrative scope and underrepresentation of LMIC contexts (6), raising the risk of selection bias. Future research should empirically evaluate innovative consent processes and adherence strategies in diverse populations (6,61). Harmonized international policies are also essential to reconcile regulatory disparities and to protect participant rights in nutrition research (6,13).

Conclusion

This review highlights the tension in dietary trials between protecting individual autonomy and maximizing research utility. Historical ethics codes—including the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report—were devised for short-term biomedical studies and thus fail to address the unique demands of prolonged nutrition interventions and cultural complexity. In practice, diet trials impose heavy burdens such as long regimens and behavior changes, leading to high dropout rates (often 20–50% or more) that existing frameworks do not anticipate (1). Regulatory disparities, particularly between GDPR and the Common Rule, further emphasize the need for harmonized international standards. Rights-based, participant-centric models are therefore needed. Dynamic consent systems, such as the blockchain-based *Dwarna* platform, enable donors to update permissions or withdraw at any time, combining flexibility with continuity of research (13). Equally important is cultural adaptation of both consent processes and dietary interventions, which has been shown to improve adherence by 25–30%. International harmonization, including material-transfer agree-

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ments and common ethical frameworks, is essential to align global research goals while safeguarding local rights (1).

Looking forward, empirical testing of innovative consent approaches and adherence-support strategies (e.g., digital reminders, educational interventions) is crucial. Stronger safeguards are also required for vulnerable groups, including community-based consent in indigenous or marginalized populations.By integrating dynamic, context-sensitive consent with harmonized oversight, dietary research can better uphold autonomy, equity, and trust while maintaining scientific validity (13,14).

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